Updated Manual 3a1

This table summarizes changes of Manual 3a1 as of 04/25/2024

Section in Manual 3a1	Description of Changes in Manual
Section 3.0	• Updated MMCC review protocol

ATHEROSCLEROSIS RISK IN COMMUNITIES STUDY

Manual 3a1

Heart Failure Cohort Surveillance Procedures
Manual of Operations

Version 1.0 of Manual 3a1
04/25/2024

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National Heart, Lung, and Blood Institute of the National Institutes of Health

FOREWORD

This manual, entitled Heart Failure Cohort Surveillance Procedures, is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus there is rather extensive list of procedures. Detailed Manuals of Operation for specific procedures, including those for surveillance, follow-up, clinic visits, reading centers and central laboratories can be found on the ARIC website https://sites.cscc.unc.edu/aric/.

Manual 3A1. Heart Failure Surveillance Component Procedures

Table of Contents

1.0 INTRODUCTION

This manual details the procedures for ARIC cohort surveillance of heart failure (HF). Section 2 describes the procedures by which potential HF events in the cohort are identified (i.e. hospital discharge lists & follow-up interview) and detailed procedures for collecting the information needed once an event has been identified. Diagnostic criteria are documented in Section 3, and review and classification procedures by the Mortality and Morbidity Classification Committee (MMCC) are described in Section 4. Section 5 outlines quality control measures and section 6 outlines the HF abstraction certification and re-certification procedures.

The following section includes some useful definitions with regards to HF.

1.1 Useful Definitions

Heart Failure

In general terms, heart failure is the inability of the heart to pump blood at a rate adequate to fill tissue metabolic requirements or the ability to do so only at an elevated filling pressure; defined clinically as a syndrome of ventricular dysfunction with reduced exercise capacity and other characteristic hemodynamic, renal, neural, and hormonal responses. Clinical practice guidelines define heart failure as a syndrome or condition characterized by: 1) signs and symptoms of intravascular and interstitial volume overload, including shortness of breath, rales, and edema or 2) manifestations of inadequate tissue perfusion, such as fatigue or poor exercise tolerance. Heart failure is often categorized as either systolic or diastolic.

Congestive Heart Failure (CHF)

CHF is characterized by breathlessness and abnormal sodium and water retention, resulting in edema, with congestion of the lungs or peripheral circulation, or both. Often the terms “heart failure” and “congestive heart failure” are used to describe the same condition.

Systolic heart failure or Systolic dysfunction

Systolic dysfunction is due to poor left ventricular contraction, usually expressed as ejection fraction (EF). In other words, systolic heart failure is heart failure due to a defect in the expulsion of blood that is caused by an abnormality in systolic function.

Diastolic heart failure or diastolic dysfunction

Heart failure patients with diastolic dysfunction (more common in the elderly) have normal left ventricular ejection fraction, the defect seem to lie in relaxation of the left ventricle and is associated with delayed filling.

Progression of heart failure symptoms

In the abstraction of the medical record using the Heart Failure Abstraction (HFA) form, section one is concerned with identifying patients with progression, decompensation, or new onset of symptoms. Progression or progressive heart failure is defined as the development of new symptoms or the worsening of existing symptoms of heart failure (e.g. pulmonary edema, shortness of breath, etc.).

Progressive heart failure may be either incident or prevalent (See below). These patients may be treated with new therapy or with the escalation of existing therapy for heart failure.

Decompensation of heart failure symptoms

In general terms, decompensation means the inability of the heart to maintain adequate circulation, marked by dyspnea, venous engorgement, and edema. Patients with decompensated heart failure are those with progressive heart failure who received treatment with intravenous medical therapy during the course of the hospitalization, including intravenous inotropic agents and intravenous vasodilators. Patients receiving intravenous diuretics are considered to have decompensated heart failure if the therapy was administered for the progression of heart failure (i.e. worsening of symptoms). Persons receiving post-operative or prophylactic intravenous diuretic therapy in the absence of progressive heart failure are not considered to have decompensated heart failure.

Event

For the purposes of completing the HFA, an "event" is the occurrence of progression of heart failure symptoms or of decompensation. Of interest for the HFA is the specific date of the event (i.e. what date did the progression or new onset of symptoms begin? See HFA item 5). In some cases the "event" date is the date of presentation to the hospital. In other cases, the "event" may have started before or after the patient was admitted. Both first (incident) events and recurrent events are abstracted.

Incident Heart Failure

An incident event is a person's first (ever) diagnosis of heart failure.

Prevalent Heart Failure

A prevalent case is a patient with a history of heart failure prior to this event.

2.0 COHORT SURVEILLANCE OF HEART FAILURE

2.1 Introduction

The aim of cohort heart failure surveillance is to identify all heart failure hospitalizations for each cohort participant and validate the diagnosis. Out-of-hospital heart failure events are also ascertained and validated by obtaining information gathered during the follow up call and data collected from the treating physician.

2.2 Identification of Hospitalized Heart Failure Events

All hospitalized events occurring in cohort members are identified. Cohort events are deemed eligible based on the following criteria: 1) a valid cohort ID; 2) discharge on or after January 1, 2005; and 3) an eligible heart failure discharge ICD-10-CM code and/or a heart failure key word in the discharge summary (see the Cohort Event Eligibility Form (CEL) form for those codes and key words). Hospital admissions may be identified through hospital discharge lists or through information elicited during follow-up interviews. Hospitalizations that are eligible but are found upon inspection to have

been for less than 24 hours should not be abstracted. If such cases appear on abstraction selection lists, a No Form (NOF) form should be completed and the reason for not abstracting the case should be noted (NOF item 3). All other eligible events are abstracted onto the Heart Failure Abstraction (HFA) form.

2.2.1 Hospital Discharge Lists

Eligible hospitalized events may be identified from the discharge lists of each local designated hospital. Discharge lists are obtained directly from the hospital and forwarded to the Coordinating Center (CC).

Using the discharge list for each hospital, all hospitalized events occurring in ARIC cohort members are identified. However, only special diagnoses require hospital chart abstraction, as described below. The entire list of cohort member hospitalizations identified from designated area hospitals will be installed into CDART. This will be done by the CC after identification of likely cohort participants from the hospital discharge lists. CDART will give the complete list of identified cohort hospitalizations from area hospitals, and can be used to furnish abstractor-specific work lists. ID numbers will be assigned in CDART for each specific hospitalization. Selected information available from the hospital list (such as hospital number, medical record number etc) will be auto-filled into some the abstraction forms.

The first task in use of CDART for cohort abstraction is to verify at the field center whether the CC's algorithm has correctly identified a cohort participant. The algorithm uses information available about the patient to assign a score related to how closely the information matches a cohort participant, and will classify hospitalizations as likely cohort matches and possible cohort matches, but in either case the field center should use information from the hospital chart and information about the cohort participant to verify the identification. The CC algorithm is designed to more often falsely suggest a match than falsely to miss a match, though may still occasionally miss a match with a cohort member, which then can be identified only as a result of follow-up interview data. If a suggested cohort match is verified as a cohort member the abstractor should proceed to abstract the required forms as indicated by CDART. If a suggested cohort match is verified as not a cohort member the abstractor should proceed to complete the NOF form.

The specific order of completion of hospitalized occurrence forms is as follows: CEL (cohort eligibility form); CHI (common hospital information), and the HFA (HF abstraction). Note that if the hospital chart cannot be found, this is registered in the CEL, and no further abstraction would be done.

Hospital chart abstraction onto the HFA form is carried out for all hospitalizations with HF ICD-10-CM primary or secondary discharge diagnosis codes (for a list of HF codes, refer to the CEL form items 11f and 11f1).

Should any mention of heart failure on the present admission (or synonyms for these conditions) be uncovered by the review of discharge summaries, hospital chart abstraction onto the HFA Form is undertaken. For all other ICD-10-CM codes, the discharge diagnoses are obtained from hospital

discharge lists and recorded on the CEL from, but hospital records are not obtained or abstracted. A number of hospitalized events for cohort members are fatal. Hospital abstracting for these events is the same as for non-fatal events.

Note that events in other institutions providing medical care (such as nursing homes, rehabilitation hospitals, long term chronic disease hospitals, hospice care facilities, and psychiatric hospitals) are not investigated.

2.2.2 Follow-up Interviews

Cohort participants may report HF hospitalizations to the follow-up interview staff. If this occurs, the follow-up staff should complete the PHF form and forward the hospitalization information to the surveillance staff for investigation. If the investigation of the hospitalization finds that the event is a true HF event, the surveillance staff assigns the event an ID (from the ID bank supplied by the CC) and enters the event into CDART. If the investigation does not find a true HF hospitalization, the surveillance abstractor enters a CEL or NOF form into CDART to indicate this was not a true event.

2.2.3 Hospitalized Events Occurring Outside the Study Community

Review of death certificates or follow-up interviews may reveal that the cohort member was hospitalized outside the study area. Hospitalization may occur outside the study area for the following reasons:

- A major hospital catchment area for the region exists outside of the area (e.g., tertiary care hospital referral centers).
- Residents who work outside of the geographic area may be admitted to an out-of-area hospital if they have an event requiring admission on an emergency basis.
- A resident may have an event while in transit outside of the geographic area for recreation or social activities.
- A cohort member may have moved from the study community.

Every effort is made to identify discharge diagnoses for such events and, if applicable, review the hospital chart. In soliciting access medical charts, a letter briefly describing the ARIC cohort study is sent to the hospital administrator as well as the director of medical records, along with a copy of the ARIC hospital record release form, signed by the participant at the time of the first exam. In some situations, it is also useful to send an abbreviated protocol. Additional contacts, including telephone conversations, with the hospital administrator or the head of the proper department (cardiology, neurology, etc.) may be necessary. Events for cohort participants who deny access to medical records are not investigated.

2.3 Obtaining Access to Hospital Medical Records

A critical feature of the process of hospitalized event identification among cohort members is obtaining information from medical records. The protocol sent to hospital administrators to access records should emphasize the fact that ARIC obtains signed hospital record release forms from cohort members. Cooperation is sought through hospital administration, medical records directors, hospital ethics committees, and influential medical staff.

It is sometimes necessary to compromise with the hospital review committees and house staff. A major consideration may be confidentiality and authorized consent to access patient's charts. Each ARIC field center works closely with its community hospitals to establish a working relationship that maximizes access to the full spectrum of eligible occurrences of heart failure that are seen at each hospital.

On occasion, there may be a need to carry out special negotiations with out-of-area hospitals where an ARIC Study cohort member was hospitalized.

2.4 Out-of-hospital Heart Failure events

Out of hospital heart failure among cohort participants is ascertained with use of the follow up phone call. When a cohort participant indicates (from follow up call) that they have had heart failure diagnosed in a physician's office and have not been hospitalized for this diagnosis, ARIC will obtain information about the diagnosis directly from the physician's office if the participant permits physician contact. A Physician Heart Failure (PHF) form is sent to the physician's office to obtain relevant information regarding the self-reported out-patient visit.

Specifically, the PHF form is completed by the physician when a participant reports that a physician has diagnosed heart failure during an outpatient visit within the last year (from date of follow-up interview). The interviewer initiates the process that enables ARIC to send that physician a request to complete the PHF (e.g. obtains the name and address of the physician). The PHF form is sent to each physician for whom the participant submits an authorization for access to information from the physician's records. Completed PHF forms received by ARIC Field Center staff are entered into the data entry system.

2.5 Forms Completed During Abstraction

Instructions for completing forms related to HF abstraction (i.e. CEL, CHI, HFA) can be found with the "Question by Question" instructions on the ARIC website (https://www2.cscc.unc.edu/aric/hf-forms). If the event was found via hospital discharge list, CDART will guide the user on which forms to complete.

Note that when abstracting for multiple events for a given hospitalization, i.e., CHD, HF and Stroke, the event ID must be the same across all forms (HRA, HFA, STR, CEL, CHI and NOF).

2.6 Summary of Hospitalized Heart Failure Investigation

The following steps summarize the forms to be completed when investigating community surveillance hospitalized HF.

Step 1: A hospitalization is identified as eligible from CDART hospital discharge list

Step 2: The medical record of the hospitalizations identified in Step 1 are examined from the medical records department at which time the event is verified for eligibility.

Step 3: Abstractors completes the CEL, CHI and the HFA if the event is eligible, else the NOF form is completed to indicate that it is not.

Step 4. Abstractor sends the following electronic medical records to the CC via LiquidFiles: echocardiogram, nuclear reports, discharge summary, catheterization report, and three chest X-ray reports starting after heart failure decompensation. Items from the discharge summary such as discharge instructions, hospital/doctor follow-up, when to call the doctor, go to the ER or when to be concerned do not need to be included. History and physical (H & P) part of the hospital record is not required, unless in the abstractor's opinion, the discharge summary is inadequate, or if the discharge summary says to go to the H & P. The abstractor should consult with the local HF committee physician if there are questions as to the need.

3.0 DIAGNOSTIC CRITERIA

3.1 Hospitalized Heart Failure

Diagnostic data abstracted from the medical record of heart failure eligible hospitalized occurrences using the HFA form include key data elements used to classify events. Hospitalizations will be reviewed by the Heart Failure Mortality and Morbidity Classification Committee (HF MMCC) to establish a diagnostic classification based on objective diagnostic data and clinical judgment. The HF MMCC review will involve completion of a HF Diagnosis (HDX) form. Based on clinical judgment of a HF MMCC reviewers (with differences adjudicated by the chair of the HF MMCC), an ARIC classification of **definite** decompensated heart failure, **possible** decompensated heart failure, **chronic** stable heart failure, heart failure **unlikely**, or **unclassifiable** will be established for each hospitalization.

3.2 Criteria for Selecting Cases for Heart Failure MMCC Review

All hospitalizations receive an independent review by two members of the heart failure MMCC. Each reviewer completes a Heart Failure Diagnosis form (HDX) where the hospitalization is classified based on clinical judgment as described in Section 3.1. The heart failure MMCC members are provided a summary of the HFA abstraction on the Heart Failure Event summary form (Appendix I). Disagreements between the two reviewer's classifications are identified by the coordinating center and sent to the Chair of the HF-MMCC for final adjudication. Hospitalizations where abstraction of

the medical record results in a skip out of the HFA form at question 3 are not reviewed by the heart failure MMCC and are automatically classified as “heart failure unlikely”.

Protocol Update

Starting with event year 2016 (in May of 2017) the HF review protocol was updated to reduce the number of physician reviews to reduce reviewer burden:

If COMP_ADHF (computer dx-acute decompensated HF) = 0 or missing, then assign the event two reviewers.

If COMP_ADHF = 1, then assign event to a single reviewer

1. If the single reviewer and the COMP_ADHF diagnosis agree, then use the single reviewer’s answer for final HF diagnosis.

• For example, if COMP_ADHF = 1 and the single reviewer assigns a HF diagnosis of A or B (HDX6 = A or HDX6 = B), then HFDIAG = HDX6.

2. If the single reviewer and the COMP_ADHF diagnosis do not agree (i.e., HDX6 = ‘C’ OR ‘D OR ‘E’ AND COMP_ADHF = 1), then assign to adjudication.

3.3 Diagnosis of Prevalent Heart Failure at Baseline

Prevalent heart failure at baseline is determined by the following criteria from data obtained during ARIC cohort visit: 1) those answering “yes” to the following question: “Were any of the medications you took during the last two weeks for HF?” (N = 83), or 2) those with stage 3 or ‘manifest HF’ by Gothenburg criteria (N = 699).

4.0 EVENT CLASSIFICATION

4.1 Introduction

The aim of heart failure investigation in the ARIC study is to establish a well-standardized process for the identification of hospitalized heart failure occurring among cohort members.

The criteria for classifying hospitalized heart failure presented here are adapted from other heart failure surveillance studies. Because diagnostic criteria used vary across studies and no consensus diagnosis strategy is currently available, the ARIC study’s classification system allows for the application of several different classification rubrics. Data collected on

hospitalized events is sufficient to apply four different classification algorithms. In addition, the HF MMCC will classify most hospitalized events on the basis of a "clinical judgment" diagnosis through review. The final ARIC classification of hospitalized heart failure is "unlikely" if all four criteria indicate no heart failure, "definite heart failure" if all criteria indicate the presence of heart failure, and the result of the Heart Failure MMCC review for all other events. If the investigation of an eligible discharge finds that a chart can not be located and a completed HFA form is not available the event is classified as "unclassifiable". Eligible discharges that skip out of the HFA form at item 3 (no indication of decompensation, progression or new onset of symptoms, no evidence in the doctor's note of heart failure and the patient is not a cohort participant), the event is automatically classified as "heart failure unlikely".

4.2 MMCC Review for Heart Failure

Cases are sent to the Heart Failure MMCC members for review if they meet criteria detailed in Section 3.0. Materials made available for reviewers include a summary of key information collected from the HFA form, and an indication of how the event meet each of the four diagnostic criteria. These data are provided on a heart failure event summary form (HF-ESF) (see Appendix I). Cases where a medical chart is not found, the ARIC heart failure classification is "unclassifiable" and the case is not reviewed by committee.

4.3 Case Law Used by the MMCC

An important function of the Heart Failure MMCC is to maintain a complete record of any classification rules to be adhered to in assigning a diagnosis based on clinical judgment. These rules or guidelines for clinical judgment are stated as case laws. The heart failure Review committee approves case laws by consensus. Case laws are reviewed annually and new case law is developed as a result of discussions with the full committee.

4.4 MMCC Final Diagnosis Forms

The HF MMCC final diagnosis form (HDX) is completed independently by two reviewers. The chair of the heart failure Review committee adjudicates disagreements. Disagreement is defined on the basis of the original reviewers answer to item 7 (i.e. clinical judgment classification as definite, possible, unlikely or unclassifiable HF). Any disagreement between reviewers for item 7 is adjudicated. For cases requiring both a MMCC review for CHD and for heart failure, the CHD review is completed first.

4.5 Linkage of Multiple Events

A characteristic of the natural history of heart failure is that it leads to multiple hospitalizations over an extended period of time. The exact onset of HF is often difficult to pinpoint, thus it may be difficult to disentangle successive admissions for the same "event" and to distinguish two or more

different events in the same person. In ARIC heart failure surveillance, each hospitalization is treated as an independent occurrence for the purposes of medical record abstraction and review (e.g. each hospitalization receives a unique identification number, each hospitalization receives a computer diagnosis and in most cases an ARIC review classification as well). The Heart failure MMCC review process treats each hospitalization as separate and does not consider linkage in its review process. Any linkage created for persons with multiple hospitalizations for heart failure are accomplished in analysis after classification.

4.6 CC Procedures for Heart Failure Reviews

This section describe the procedures taken by the CC staff to ensure abstracted event review by the MMCC.

4.6.1 Heart Failure Reviews

The CSCC generates the MMCC Event Summary Forms in the Data Management Program (MGP). The Event Summary Form is combined with the medical records by the MGP. The steps taken at CSCC in processing Cohort Surveillance MMCC materials are as follows:

A. **Check Case Material Documents at Arrival at CSCC:** Upon arrival of documents at the CSCC via LiquidFiles, the PDF should be checked for ID number to make sure it matches the number labeled on the file. Once the file has been checked, it can be moved to the MMCC Scanned Materials folder where the MGP will search for it. Queries for missing materials not received are generated in the MGP and sent to the field centers.

B. **Assigning Reviews:** The MMCC review packet containing the case materials is created during the MGP and loaded into CDART using a CSV file. The CSV file is also used to make reviewer assignments. The reviewer code and date assigned are completed and then the CSV file is loaded to CDART to be automatically loaded into the HDX form. An email is sent to the reviewer with the CDART link and the date that reviews are expected to be completed.

4.6.2 Adjudication of Heart Failure Reviews

Adjudication is required if the classification in Question 6 (The overall heart failure diagnosis) disagrees between two reviewers for Cohort Surveillance. The reviewer answers are compared to each other by the MGP. Cases are assigned via CSV file with reviewer code and date assigned and uploaded to CDART. The HF Committee Chair's adjudicated classification becomes the event's final ARIC classification.

4.6.3 Monitoring Completion of HDX Forms

Reviewers who do not meet expected deadlines are reminded of their tardiness. This becomes imperative closer to the event year closeout. The chair may need to become involved to get reviewers to complete their cases.

4.6.4 Monitoring Consistencies of New Reviewers

When new reviewers have been certified and are ready to begin reviewing cases, the number of HF events is kept low. As original reviewers, they are paired with experienced reviewers. Feedback to the new reviewers on the cases needing adjudication is helpful.

5.0 QUALITY CONTROL MEASURES

5.1 Quality Control for Heart Failure record abstraction

A sample of hospitalizations is re-abstracted by a different abstractor within the same field center. Each abstractor re-abstracts 1 record each month that were originally abstracted by another abstractor at their same field center. One of these hospitalizations each month should be selected from those hospitalizations with a HF discharge code. Hospitalizations for re-abstraction will be selected by the field center from their list of eligible cohort hospitalization.

Graphs produced monthly are available on the password protected area of the ARIC website (https://views.cscc.unc.edu). The QC summaries include but not limited to:

- Percent Disagreement in Repeat Abstraction for the Diagnosis of Heart Failure Prior to Hospitalization Variable, by Year and Center
- Percent Disagreement in Repeat Abstraction of Section 0: (HFA) by Year
- Percent Disagreement in Repeat Abstraction of Section I: Screening for Decompensation (HFA) by Year
- Percent Disagreement in Repeat Abstraction of Section II: History of Heart Failure (HFA) by Year
- Percent Disagreement in Repeat Abstraction of Section III: Medical History (HFA) by Year (
- Percent Disagreement in Repeat Abstraction of Section IV: Physical Exam-Vital Signs (HFA) by Year

5.2 Quality Control for MMCC Reviews

Graphs produced monthly are available on the password protected area of the ARIC website (https://views.cscc.unc.edu). The QC summaries include:

- Number of all-time original HF MMCC reviews for active reviewers
- Number of all-time original HF MMCC reviews among active reviewers, by year
- Proportion of events with disagreement between two reviewers (all reviewers)
- Disagreement rates per reviewer
- Number of all-time HF MMCC adjudications for active reviewers
- Disagreement rates with adjudicator, by reviewer
- Disagreement rates with adjudicator/other reviewer, given that the adjudicator has agreed with one of the reviewers

6.0 CERTIFICATION FOR HEART FAILURE ABSTRACTIONS

6.1 Introduction

ARIC Study staff involved in medical record abstraction must be certified before they begin record abstraction in the field. The certification process involves participation in a week long centralized training workshop held at the CC as well as satisfactory performance on a certification exam. The following describes the certification process.

6.2 Training

Expectation

In order to be certified for HF abstraction, new abstractors must participate in an initial week long centralized training workshop. Participation in the workshop also includes review and completion of a pre-training workbook. The pre-training workbook includes important background information about the clinical presentation and treatment of HF, detailed question by question instructions for completing the HFA form, practice exercises in completing the diagnostic test evaluation section of the HFA, and two full medical record abstraction exercises complete with answer keys. New abstractors are expected to review these materials and gain experience with reviewing medical documents and completing the HFA form prior to the central training.

During the central training, abstractors will be expected to participate in the group discussions and abstraction practice opportunities. During the central training, abstractors will also be instructed on navigation of the data entry system.

Performance measure

Successful completion of the training phase of certification will be measured by participation in the abstraction exercises and involvement in the group discussion of the HF abstraction protocols and instructions as well as completion of practice exercises assessed by field center supervisor.

6.3 Certification Exam

Expectation

After successful completion of the training phase, an abstractor will be eligible to sit for the certification exam. The exam will consist of abstracting two medical charts using the HFA form. The abstraction of the exam charts may be completed using the electronic data entry system or paper forms if preferable. Abstractors wishing to be certified in HF records may take the exam at a time of their choosing within two weeks of completing the training phase. Exam charts must be completed independently.

Performance measure

The two completed exam HFA forms will be scored relative to a key created by consensus of two members of the HF Surveillance Committee, one of which will be the Chair of the Committee. Scoring of the exam charts will be weighted to give more weight to those items on the HFA form deemed to be most critical (e.g., Section I: Screening for decomposition or new onset of symptoms, and components of the various diagnostic classification algorithms in the sections III, IV, V, and VI). An overall abstraction quality score assigned by the Chair of the HF Committee will also be factored in to the final score. In order to qualify for Certification, abstractors must pass both medical charts per criteria set by the Chair of the HF Committee. If they fail in either one of the charts, they will need to retake the certification exam to be certified.

Abstractors may retake the certification exam a maximum of two separate times. Retaking the certification exam will involve review of a different set of two medical records, not a reexamination of the same medical records. A two day interval is required before a reexamination will be provided. Staff have up to one month after their first exam to retake the exam. Staff not successfully completing the certificate exam after three attempts will not be certified.

Appeals of the abstractors score will be considered. Decisions of the Chair of the HF Surveillance Committee are final.

6.4. Re-certification

Annual required re-certification training for HF abstractors will be conducted either at the CC or via webinar. In this process, abstractors will be required to complete abstraction of a set of four medical records prior to the re-certification training. All abstractors will review the same four medical records. Question by question agreement amongst all abstractors will be reviewed and discussed during the re-certification training. Participation in re-certification training is required for staff to retain their certification for HF abstractor status.

Appendix I. Heart Failure Event Summary Form

A. ARIC Identifiers

HF Event ID	Cohort ID	Gender	Age at Discharge	Date of Event	Admission Date	Discharge Date	Primary Discharge Code
		M	81	.			J18.9

Surveillance ID:

List of all ICD Hospital Discharge Index Codes (CHIA2a-2z3):

List of all ICD Hospital Discharge Summary Codes (CHIA9a-9z3):

J18.9	J96.01	J98.11	J21.9	T17.890A	E11.65	T38.0X5A	I13.0	E11.22	N18.3	I50.9	I48.0	I71.2
I95.1	M19.011	M25.551	I44.0	I44.4	E78.5	R42	Z91.81	E66.9	F32.9	Z68.29	Z79.4	Z86.73

B. Selected data elements from hospital record.

I. SCREENING CRITERIA FOR COMPLETE CHART ABSTRACTION:

Increasing or new onset SOB:	Yes		
Increasing or new onset edema:	No/NR		
Increasing or new onset paroxysmal nocturnal dyspnea	No/NR	Increasing or new onset orthopnea	No/NR
Increasing or new onset hypoxia	Yes		
MD note indicates reason for hospitalization was heart failure	No/NR		

II. HISTORY OF HEART FAILURE (HF):

Previous diagnosis	No/NR
Previous hospitalization	No/NR
Previous treatment	No/NR
History of MI	No/NR
History of hypertension	Yes
Discharge status	Alive

III. IN-HOSPITAL HEART FAILURE (HF):

New onset or progression/exacerbation of HF	
At the timeof admission	Yes
During this hospitalization	No/NR

IV. EJECTION FRACTION (EF):

Prior to this hospitalization	EF%
Lowest Ejection Fraction(LVEF)	81
LV Function-Qualitative Description	Missing
During this hospitalization	EF%
Transthoracic Echocardiogram	60
Transesophageal Echocardiogram	.
Radionuclide Ventriculogram	.
Coronary angiography	.

V. BNP LEVELS:

	Worst	Last				
ULN* BNP	96.6	96.6	100			

VI. PERTINENT CHEST X-RAY FINDINGS:

Alveolar/pulmonary edema	No/Unknown
Interstitial pulmonary edema	No/Unknown
Alveolar infiltrates	No/Unknown
Unilateral pleural effusion	Yes
Bilateral pleural effusion	No/Unknown
Cardiomegaly	No/Unknown
Upper zoneflow redistribution/cephalization	N
o/Unknown Congestive heart failure	N
o/Unknown	
Pulmonary vascular congestion	No/Unknown

Appendix II. Instructions for Sending Duplicate Hospital Records to the CC

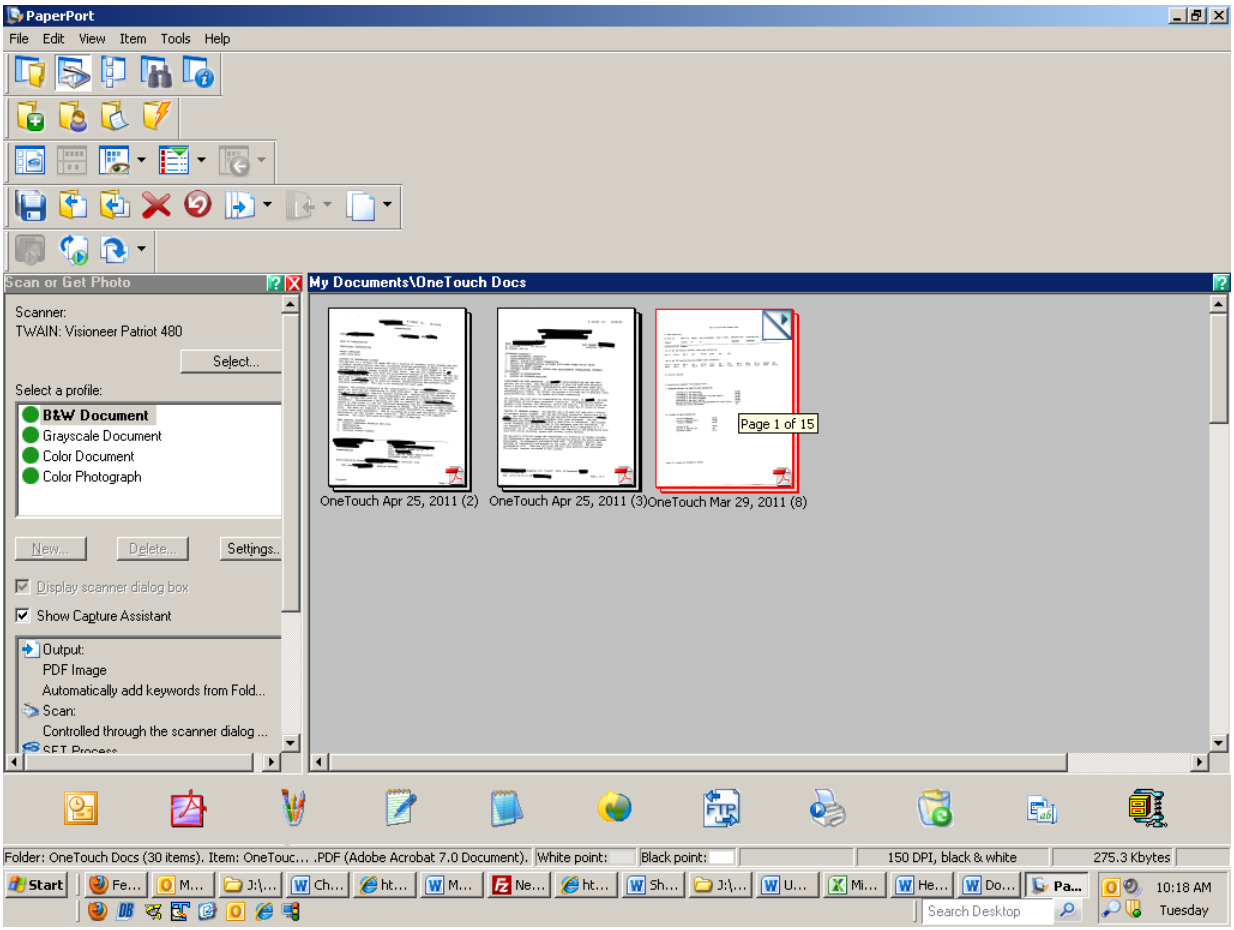
When a significant number of medical records have been prepared, they are put in numeric order and sent to the CC File Center via a secure Liquid Files account. If CC requires hospital records for materials not sent for a particular patient's event these are also prepared and transferred in a similar fashion.

Naming Convention for Hospital Records
CHD: Surveillance ID followed by "C"
Stroke: Surveillance ID followed by "S"
Heart Failure: Surveillance ID followed by "H"
Serum Creatinine: Surveillance ID followed by "K"

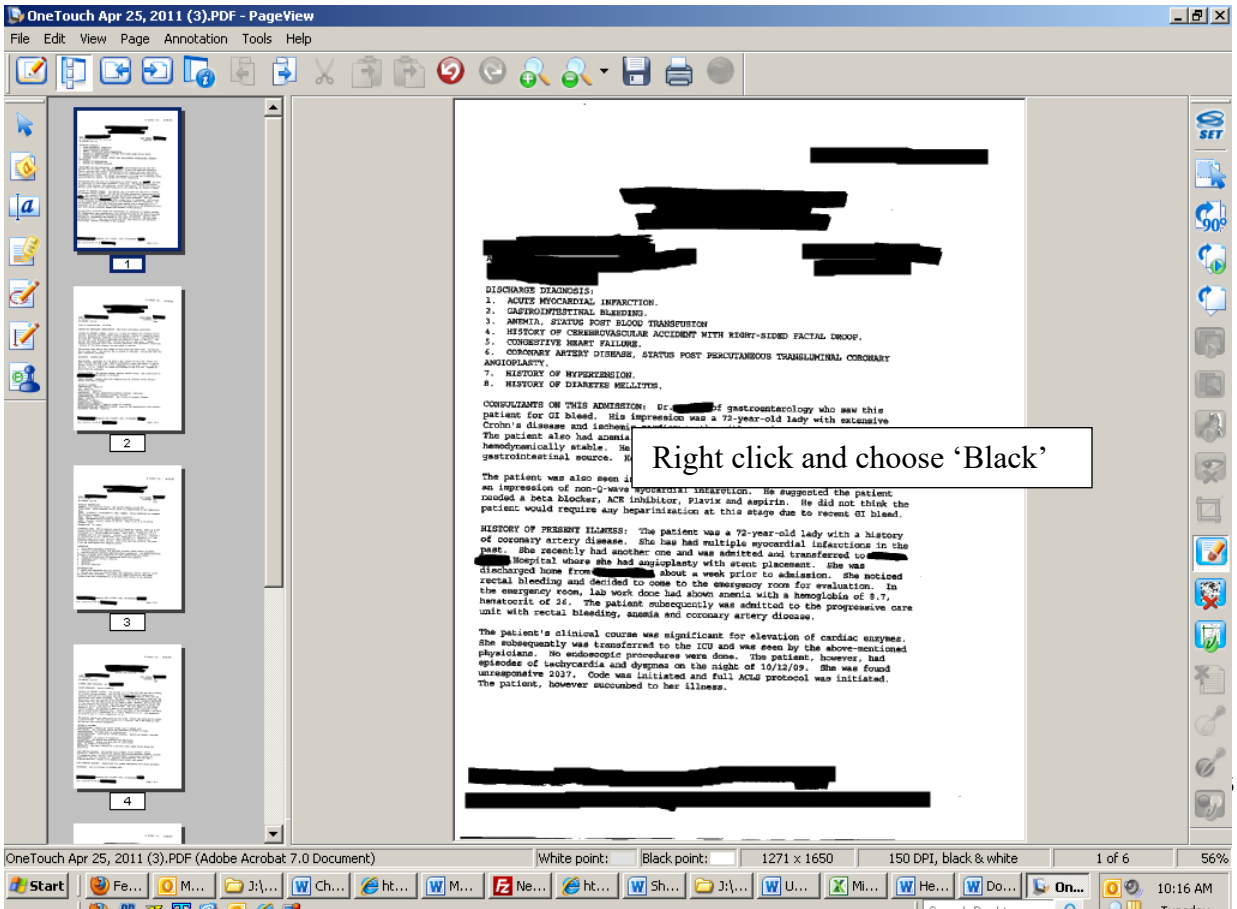
Preparing Paper Files to send to the CC
Scan all the appropriate materials for each event using your scanner set to black and white document. Include the completed "Checklist for Hospital Event Materials" as a cover page. Cut and paste the event id from the Hlist report from the DMS onto the electronic version of the checklist. If using a paper version of the checklist, write the event id in by hand. Before uploading the documents you will need to blind the documents of PHI using a redacting tool; like the one in Adobe.

List of Items for Blinding
The following items should be blinded for all duplicate materials sent to the CC.

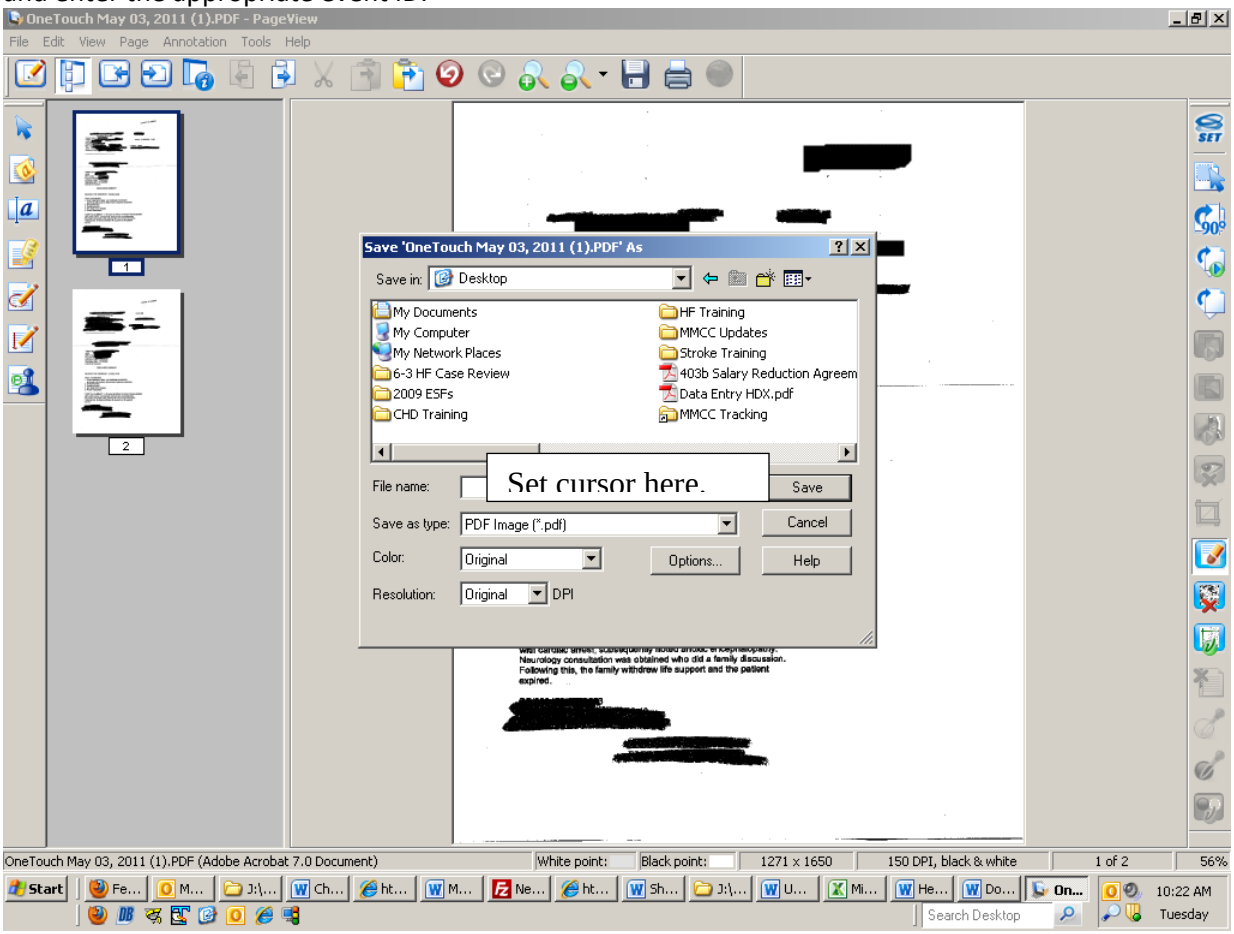
- Names of the Patient or of the Patient's Relatives, Employers, or Household Members. (Their initials need NOT be redacted. Names/Initials of hospital/medical care personnel do NOT need to be redacted.)
- Social Security number
- Date of Birth
- Street address, city county, precinct, zip code, and equivalent geocodes
- Telephone, Fax, Drivers License or plate numbers
- Email addresses
- ~~Hospital name~~
- Medical record number
- Health plan ID numbers
- Account numbers



Blind the documents using the eraser tool (set to black) found in the PaperPort software.



Save the materials as a PDF in a secure location. Choose File/Save As/Place curser in the File Name box and enter the appropriate event ID.



Preparing Electronic Files to send to the CC

The Coordinating Center recommends using Adobe Acrobat Professional Version 8 or higher to create PDFs of your electronic files.

Each field center may receive their materials in a number of different formats. Follow this link for guidance on how to convert many common file types to PDF.
http://helpx.adobe.com/en/acrobat.html

This software package also includes a redacting tool. Follow this link for instructions.
http://helpx.adobe.com/acrobat.html?content=WS5E28D332-9FF7-4569-AFAD-79AD60092D4D.html

Scan the completed "Checklist for Hospital Event Materials" as a cover page and combine with the duplicated materials into a single PDF. Add a top right header to the PDF document that contains the event id.

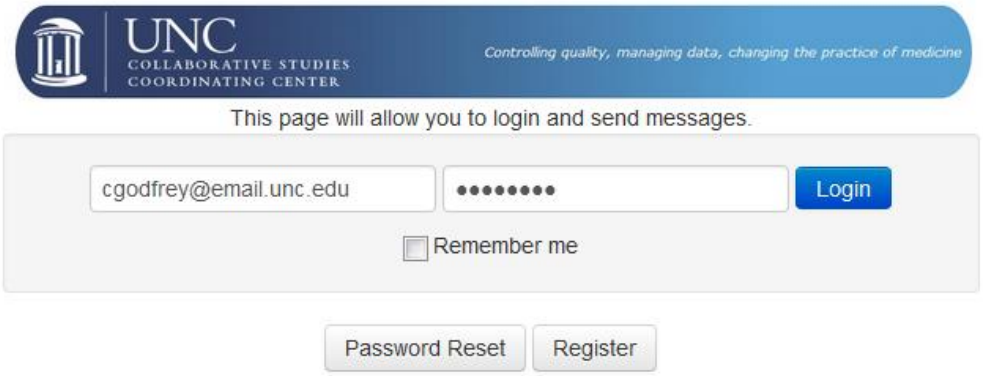
Follow this link for instructions on using adobe.
http://helpx.adobe.com/en/acrobat.html

After creating and blinding the PDF choose File/Save As and place the curser in the File Name box. Choose the appropriate folder in the Save In drop down and scan the bar code for that ID.

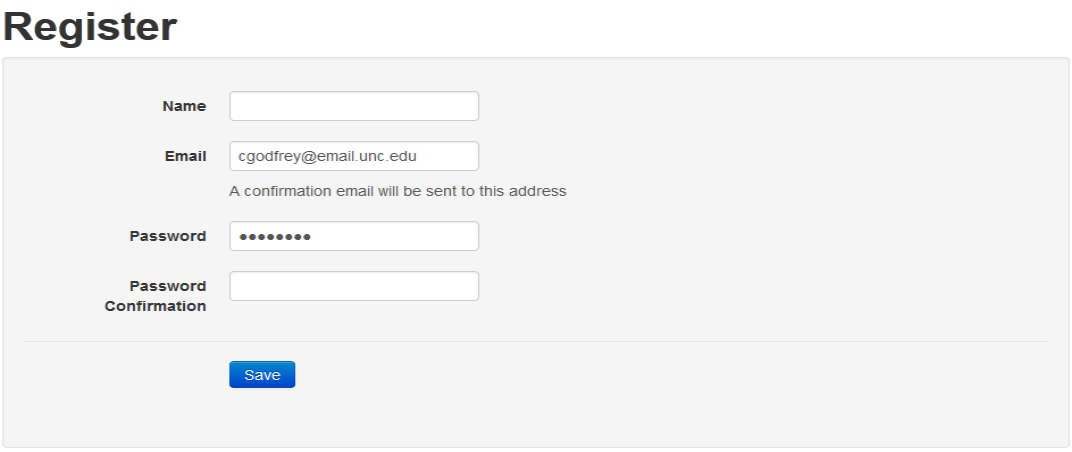
Utilizing the CC File Center to send documents to the CC

Creating a Liquid Files Account

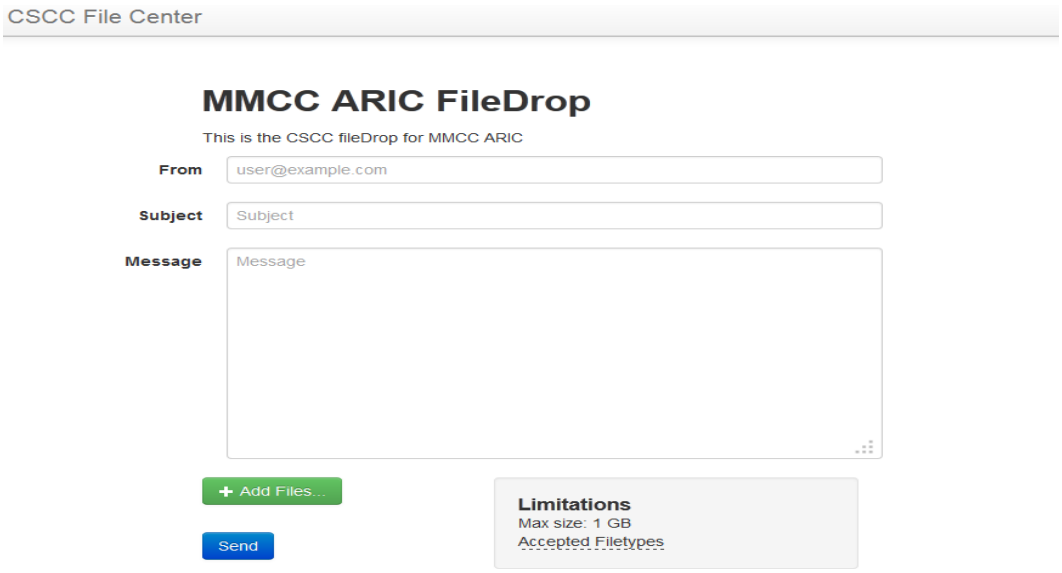
Go to the website:
https://csccex.cscc.unc.edu/



Click on Register and to create a new account. Once your account has been created you will receive a confirmation email.



Fill in name, email address and password.
Once the account has been created, hospital records in PDF format can be sent to the CC through this weblink: https://csccex.cscc.unc.edu/filedrop/MMCCARIC



Click the '+Add Files' to add files to be sent. You can review the files you are sending by looking at the attached files list before you send. When you have completed uploading all of the files click 'send'.